

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

POLYMER TECHNOLOGY SYSTEMS,
INC.

Plaintiff,

v.

CIVIL ACTION NO. 1:10-cv-0061 LJM-TAB

ROCHE DIAGNOSTICS CORPORATION,
ROCHE DIAGNOSTICS GMBH, ROCHE
DIAGNOSTICS OPERATIONS, INC.,
ROCHE OPERATIONS LTD

Defendants.

**DECLARATION OF ROBERT S. HUFFSTODT IN SUPPORT OF PLAINTIFF'S
MEMORANDUM IN RESPONSE TO DEFENDANTS' MOTION TO COMPEL
ARBITRATION AND DISMISS THE ACTION AND FURTHER IN SUPPORT OF
PLAINTIFF'S MOTION FOR AN ORDER ENJOINING DEFENDANTS FROM
ARBITRATING INFRINGEMENT**

I Robert S. Huffstodt, based upon my own personal knowledge, declare as follows:

1. I am President and CEO of Plaintiff Polymer Technology Systems (PTS) of Indianapolis Indiana, where I oversee all aspects of the business, with the persons handling sales, marketing, finance, accounting, product development, engineering and manufacturing reporting directly to me. I joined PTS in July of 2001, became President in October 2001, and CEO in 2002. Until about May 2008, I directly oversaw the product development, engineering and patent functions at PTS. I personally negotiated and signed the Stipulated Final Judgment, Settlement Agreement and License Agreement referred to in this Declaration.

2. I am over the age of 18 and have personal knowledge of the facts stated herein and can competently testify as to those facts if requested to do so.

3. I provide this Declaration in support of Plaintiff's Memorandum in Response to plaintiff's Memorandum in Response to Defendants' Motion to Compel Arbitration And Dismiss

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The Action And Further In Support Of Plaintiff's Motion For An Order Enjoining Defendants From Arbitrating Infringement ("PTS' Memorandum").

4. Polymer Technology Systems (PTS) is an Indianapolis, Indiana corporation which designs, manufactures and sells throughout the world dry diagnostic test strips and other products used to read the strips. PTS is rapidly growing with current sales getting close to twenty million per year.

5. We believe that PTS is the technological leader in the field of dry test strips using reflectance meters, and, based at least on the number of recent US patents (eight), this would certainly be true.

6. Roche Diagnostics GmbH is a Company based in Switzerland that is a competitor to PTS in the dry diagnostic test strip market, though our technologies are different in important ways. Roche Diagnostics Corporation is an Indianapolis company, formerly Boehringer Mannheim GmbH, that was acquired by Roche Diagnostics Corporation in about 1999. Together, Roche Diagnostics GmbH and Roche Diagnostics Corporation are referred to herein as "Roche". Roche has the dominant market share in the field. Sales of Roche in just North America are reported to be 2.6 Billion dollars per year.

7. In 2003, Roche was the owner of a number of US patents originally filed in the 1980's and early 1990's. See US Patents Nos. 4,816,224 (the '224 patent); 5,366,609 (the '609 patent); 5,426,030 (the '030 patent); 5,580,743 (the '743 patent); 5,786,164 (the '164 patent); 6,171,849 (the '849 patent); and 6,214,570 (the '570 patent) attached to Roche's Exhibit 2. The '609 patent is also attached to PTS' Memorandum as Exhibit C, Attachment 1. Note that the last five patents ('030, '743, '164, '849, and '570) all have the same specification and are based on a German application filed in 1989, so these patents represent only three separate patent disclosures.

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8. In 2003, Roche sued PTS in Indianapolis for infringement of five United States Patents including the '224 patent, the '609 patent, the '164 patent, the '849 patent, and the '570 patent (collectively referred to herein as "The Roche 2003 Litigation Patents") in Civil Action No. 1:03-CV-0848 JDT-WTL (hereinafter referred to as the 2003 Litigation)(Roche Exhibit 2).

9. PTS never answered the complaint in the 2003 Litigation, or made any claims, counterclaims, defenses, or requests for relief of any kind.

10. In 2003, PTS was on the verge of bankruptcy: it was overdue on payment of its bank loans, it owed the Internal Revenue service money, and was behind in payment of its employees. In November 2003, PTS laid off more than half of its workforce.

11. In the summer of 2003, Roche invited PTS to Germany to negotiate settlement of the 2003 litigation. There Roche presented us with already written Agreements showing their terms. Roche accepted few changes, but when PTS insisted on a change, such as not agreeing to infringement of the patents, Roche wrote up the language and presented it to us. PTS again met with Roche in New York City on about October 29, 2003.

12. Roche's initial position was that it wanted PTS to admit infringement of all five of the patents in suit, and to pay royalties on all its products. PTS was not about to agree to this because, except for the '224 patent, Roche's evidence of infringement was weak. However, claims 1, 3 and 4 of Roche's '224 patent literally read on the description of PTS' HDL strips as described at col. 9, lines 5 – 21 of PTS' US Patent No. 7,087,397 attached hereto as Exhibit A, Attachment 1.

13. After several months of negotiation, PTS figured out that what Roche really wanted was the royalties on all PTS products so it could declare complete victory.

14. So PTS agreed that it infringed "one or more claims" of the patents in suit, and

further agreed that if it infringed at least one claim of the five patents in suit, it would pay royalties on the “system” which, at that time, included all of its products.

15. On December 18, 2003, Roche and PTS signed a Settlement Agreement and a License Agreement and agreed to a Stipulated Final Judgment. The Settlement Agreement is Roche’s Exhibit 4 attached to Roche’s Memorandum and the License Agreement is Roche’s Exhibit 5 attached to Roche’s Memorandum. A true and correct copy of the Stipulated Final Judgment is attached PTS’ Memorandum as Exhibit C, Attachment 2.

16. The Stipulated Final Judgment stated that PTS had infringed one or more claims of the Roche 2003 Litigation Patents. Neither the Stipulated Final Judgment nor any other document signed by the parties indicates any specific patent or claim was infringed by PTS.

17. PTS executed and fulfilled all terms of the Settlement Agreement, as well as all the terms of the License Agreement.

18. The Roche patents were in three general areas: The ‘030, ‘743, ‘164, ‘849, and ‘570 patents covered a high density lipoprotein (HDL) dry test strip. The ‘224 patent, covered a dry test strip with a fiberglass layer. The ‘609 patent, which is the subject of this litigation, covered a biosensing meter.

19. Both the PTS and Roche technologies employ a meter and a variety of dry test strips to which a blood sample is applied. In both technologies, the meter runs a test process on the strips to provide a measurement of the concentration of an analyte, such as cholesterol. But otherwise the meters are different.

20. As stated in the ‘609 patent, the sense means applies an excitation voltage (trace 76, FIG. 4) is applied to excitation electrode 24 causing a reverse reaction in well 20. (‘609 patent [PTS’ Exhibit A], col. 7, lines 10-15). Further, claim 1 of the ‘609 patent contains

limitations added during prosecution which specifically include the active control of the operation of the sense means during the test. Since the meter biochemically interacts with the sample, the Roche meter is a classic biosensor.

21. In PTS' meters the sense elements in the PTS meter do not chemically interact with the sample, like the sense element in the '609 patent does. In the PTS system, the sensing is performed by an LED, a photodiode, a sense amplifier and an analog to digital (A to D) converter. The LED shines light on the strip, which light is reflected from the strip, sensed by the photodiode, amplified by the sense amplifier, and digitalized by the A to D converter.

22. In the PTS system, a color is developed in a Trinder reaction in a reaction layer. The color is detected by the photodiode and tells how much cholesterol in the strip. The amount of color does not depend in any way on the sensor, i.e., the LED, photodiode, sense amplifier and A to D converter. The color is the same whether it is measured or not.

23. The PTS system essentially works the same as the human eye and brain works in determining the color of a book. The human eye can tell if it is a red book or a green book by sensing the reflected light. The color of the book does not change just because the human looks at it.

24. Likewise, the color of the strip in the PTS meter does not change just because the LED shines on it and the photodiode detects its color.

25. Thus, the PTS meter is not a biosensor. There is no chemical interaction between the LED and photodiode and the sample.

26. Since the settlement of the 2003 litigation, PTS has had two major redesigns of its meters: one redesign completed in August 2005 resulted in the 2.3x series meters, and the second redesign which we began marketing in February 2009 resulted in the 2.5x series meters. In the

2.3x series meters, the circuit and software of the meter were changed so that the LED of the PTS meter was selected by the meter before the test started and pulsed at a frequency set before the test started, neither of which changed during the test. Further, the photodiode has always been passive, the sense amp in the 2.3x meter never changes, and the A to D converter parameters in the 2.3x meter are hard wired. That is, by August 2005, none of the parameters that control anything in the sensing system (referred to as a “sense means” in the ‘609 patent) were downloaded during the test.

27. In September 2005, this Court entered an Order on Claim Construction in Case 1:04-cv-01187-LJM-VSS, which we refer to as the HDI Litigation. This claim construction held that the sense means includes an electrode and sense amplifier that are controlled by microprocessor using data downloaded from the pluggable memory during the test. Because the PTS meter does not have a sense means as described and claimed in the ‘609 patent as constructed by this Court, by the beginning of 2006, PTS understood that its meter did not infringe the ‘609 patent.

28. Even though PTS’ meter did not infringe the ‘609 patent, PTS paid royalties on it, because the License Agreement required PTS to pay on all its products if just one of the products infringed any claim of the seven Roche patents in the License Agreement.

29. Roche’s old dry test strip technology, shown in FIG. 1, required blood to be added to one side 13 of a strip, and then, after a certain time sufficient to allow the test to proceed, a second part 16 of the of the strip was contacted to the first part to complete the test.

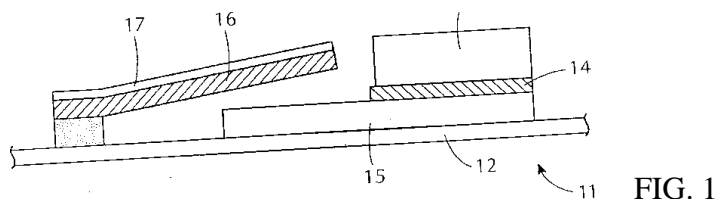


FIG. 1

30. In PTS' newer dry test strip technology, shown in FIG. 2, blood was simply placed into top port 34 of the strip, and a short time later, the test was read through the port 26 at the bottom of the strip. Note that the hinge 22 and plate 18 comprise a rigid plastic casing that is closed at the time of manufacture to trap and protect the stack 14, and is not moved during the test.

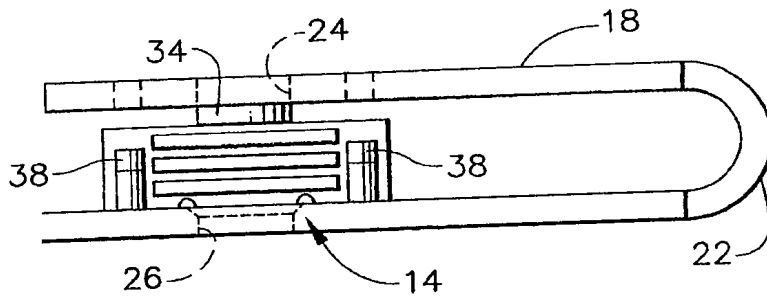


FIG. 2

31. By filing continuing applications with newly added claims after PTS' newer technology was disclosed by PTS in US Patent No. 5,597,532, attached hereto as Exhibit A, Attachment 2, by the time of the settlement of the 2003 Litigation, Roche was able to place before the US Patent and Trademark Office and get claims which arguably read on PTS' HDL strips.

32. However, all the Roche claims in its HDL dry test strip patents required the unwanted cholesterol to be precipitated. See the claims in the '030, '743, '164, '849, and '570 patents attached to Roche's Exhibit 2.

33. In the time period from about January 2004 through early 2006, PTS developed a completely new dry test strip process that did not include precipitation. An FDA submission was required because the strip chemistry was unlike any strip previously approved by the FDA. The FDA submission was made in 2005 and approved in early 2006.

34. Several US patents have issued on PTS' new processes which do not use precipitation.

35. PTS' non-precipitating method is superior to the old precipitating methods because, in the old process, the precipitants clogged the pores in the fiber layers and prevented free flow of the cholesterol to the detecting layer.

36. By the end of March 2006, PTS had discontinued making HDL dry test strips with the old precipitating technology and all its HDL test strips used the new non-precipitating technology that clearly did not infringe any of the five Roche HDL patents.

37. By April 1, 2006, PTS was also certain that its meter did not infringe the '609 patent and understood that there was an order of this Court that so held.

38. However, PTS continued paying royalties because it was still using fiberglass some of its strips. But, on March 28, 2006, the '224 patent, which included the claims reciting a fiberglass layer, expired. Thus, as of March 28, 2006, PTS clearly did not infringe any claim of any of the seven Roche patents listed in the License Agreement.

39. Knowing that the products and circumstances had changed, and there no longer could be any argument that any of its products infringed any of the Roche patents in the License Agreement, PTS stopped paying royalties on April 1, 2006.

40. PTS fully informed Roche of the reasons it stopped payment of royalties.

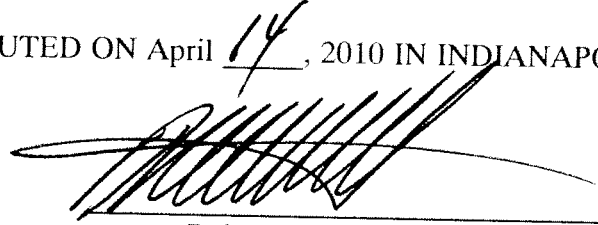
41. On March 2, 2007, this Court entered its Order on Cross Motions For Summary Judgment. PTS understood that under this order, a meter that does not access the pluggable memory during the test to get the data to control the sense means cannot infringe the '609 patent.

42. In 2008, PTS did a planned complete redesign of its meter, including both the electrical circuit and the software. The new design includes a large internal memory that can hold all of the data in the pluggable memory.

43. To make doubly sure that there could be no infringement of the '609 patent, in the

new design, all of the data is downloaded from the MEMo Chip™ (pluggable memory) prior to the start of each test, and the microprocessor then accesses the data from its internal memory, not from the external code chip.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES OF AMERICA THAT THE FOREGOING IS TRUE AND CORRECT AND THAT THIS DECLARATION WAS EXECUTED ON April 14, 2010 IN INDIANAPOLIS, INDIANA.

A handwritten signature in black ink, appearing to read 'R. Huffstodt', is written over a horizontal line.

Robert S. Huffstodt
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